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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/640,853

08/13/2003

Randall V. Sparer

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07/27/2010

MUETING, RAASCH & GEBHARDT, P.A.

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/640,853	Applicant(s) SPARER ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-150 is/are pending in the application.
- 4a) Of the above claim(s) 90,105-133 and 139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89,91-104,134-138 and 140-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/24/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments to the claims filed 05/24/2010 have been entered. Any objection/rejection from the previous office action filed 01/22/2010 not addressed below has been withdrawn.

Election/Restrictions

Applicant's election of the species of polyurethane and polyphenylene oxide in the reply filed on 05/24/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The examiner has rejoined claim 92 since it now read on the elected species.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252), for the reasons set forth in the previous office action filed 09/11/2008 and 08/25/2009.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483), for the reasons set forth in the previous office action filed 09/11/2008 and 08/25/2009.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1), for the reasons set forth in the previous office action filed 09/11/2008 and 08/25/2009.

Claims 89,91-97,99,101-103,134-138 and 140-143,145,147-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Atala (US 6,576,019), for the reasons set forth in the previous office action filed 01/22/2010.

Response to Arguments

Applicant's arguments filed 05/24/2010 have been fully considered but they are not persuasive.

Applicants assert there is no teaching or suggestion in Sirhan, Whitbourne, Hossainey or Atala on tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend with the recited relationships of solubility parameters of the polymers and active at a predetermined amount over a period of time not controlled by porosity.

The examiner notes the above argument but does not find it persuasive. The claimed method of tuning the delivery of an active agent recites the same steps of forming a polymer blend with the recited relationships of solubility parameters of the polymers and active found in previous claim sets. Since the implants described by Hossainey, Whitbourne, Sirhan and Atala teach the same types of polymer blends and active agents it is inherent that the same composition will have the same the same properties including its ability of "tuning" the active agent, the claimed solubility parameter relationships and the release of the active. To meet the claimed method the

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examiner conducted his search based upon the active steps recited within the claims, that is a method of receiving a first and second polymer as claimed in combination with the claimed active to form an implantable device. The recited "tuning the delivery of the active" was seen as being met if all of the active steps recited in the claim body were met. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Applicants assert that the references above teach several different classes of polymers, thus applicants surmise that the references each specify a vast number of individual polymer species. Applicants further contend that there is no guidance within the references above to select the same polymer blend claimed by applicants with the recited relationships of solubility parameters.

Firstly with respect to Sirhan and Atala the polymer blend described is claimed, all US patents are considered valid thus, there is adequate guidance and direction for the claimed polymers. As mentioned numerous times in actions in the past and again herein both the Hossainey and Whitbourne references clearly teach the same first and second polymers claimed by applicants. Whitbourne claims polyvinyl acetals and acetates, acrylic polymers, methacrylic polymers meeting applicants claimed second

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polymer and also claims an active agent that included several cellulose derivatives and polyurethanes as detailed within the disclosure of the specification. Hossainey claims several cellulose derivatives within the claims and the description of the specification list polyamides, polyesters, polymethacrylates polyolefins, and ethylene methyl methacrylate copolymers as useful ingredients in the polymer film. Thus from the claimed invention of Whitbourne and Hossainey and the descriptions of other polymers that are useful within their respective specifications one of ordinary skill in the art would have readily envisaged from the teachings of Whitbourne and Hossainey applicants claimed drug delivering polymer blend and the method to produce it. Also in regards to Whitbourne and Hossainey, the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed. Furthermore while both the references above teach and claim numerous polymer blends, this only supports the fact that polymer blends are a well known and very mature field. One of ordinary skill in the art would know from the teachings of the references and what is generally well known and established in the art that numerous polymers can be blended or mixed together to form coatings for medical devices. In the same regard applicants specification and claims are also broad in the number of types of polymers that can be blended, but the examiner has concluded that applicants have provided enough written description and showed enablement since the field of polymer blends is well known and very mature field, thus there are currently no 112 1st paragraph rejections over the breadth of the claims. However applicants argue,

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contradictory, that a prior art reference which is similar to their claimed invention in that it also describes numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible. A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As detailed above the examiner concluded from the prior art that polymer blends used as coatings for medical articles is a very mature field, thus the breadth of the number of possible combinations would not preclude one of ordinary skill in the art from envisioning nearly any combination of polymers that are described as being capable of being blended. Thus the examiner believes there is adequate support and guidance within each reference so that one of ordinary skill in the art would have readily envisaged applicants claimed invention from the teachings of Hossainey and Whitbourne.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 89,91,93-104,134-138,140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed., Elsevier., for the reasons set forth in the previous office action filed 08/25/2009.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in

view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 09/11/2008.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed., Elsevier, for the reasons set forth in the previous office action filed 09/11/2008.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 09/11/2008.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed, for the reasons set forth in the previous office action filed 09/11/2008.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 09/11/2008.

Claims 89,91-97,99,101-103,134-138,140-143,145 and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 6,576,019 B1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed, for the reasons set forth in the previous office action filed 01/22/2010.

Claims 89,91-97,99,101-103,134-138,140-143,145 and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 6,576,019 B1), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 01/22/2010.

Response to Arguments

Applicant's arguments filed 05/24/2010 have been fully considered but they are not persuasive.

As in their remarks above applicants contend that there is no teaching or suggestion in Hossainey, Whitbourne, Sirhan or Atala on tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend with the recited relationships of solubility parameters of the polymers and active at a predetermined amount over a period of time not controlled by porosity.

The examiner for the reasons set forth above respectfully disagrees.

Applicants further contend in regards to claims 102 and 148 that the cited references do not describe how delivery of the active occurs predominantly under permeation control.

Once again the examiner relies on the fact that the reference describes the same type of composition therefore any claimed properties of that composition are met including delivery of the active. A composition and its properties are inseparable.

Lastly applicants assert that the references above do not provide a teaching or suggestion that would direct one of ordinary skill in the art to select applicants claimed subset of polymer and active agent combinations from the innumerable combinations described within each. Applicants purport the case law of KSR International Co. v. Teleflex Inc. (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007) and Sud-Chemie, inc v. Multisorb Technologies support their contention that while the references above describe classes of polymers that may be blended it is taken from innumerable species that have different properties including solubility parameters and without guidance for this selection the combinations above cannot render applicants claims obvious.

The examiner respectfully disagrees. While the examiner notes the case law provided above the current issue differs from the specific cases cited above. The examiner relies on his remarks above regarding Hossainy, Whitbourne, Sirhan and Atala as to why one of ordinary skill in the art could have readily envisaged or been obvious to select the claimed blend. Regardless applicant's remarks seem to only point out that guidance is not provided in the primary reference when clearly the rejections were made in combination with the secondary references Van Krevelen or Coleman. Clearly as set forth in the previous office action the primary references above are silent in regards to solubility parameters of the polymers and actives; however both Van Krevelen and Coleman describe how to calculate solubility parameters and use them to

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predict miscibility. Both Van Krevelen and Coleman describe that when two polymers are close in their solubility parameter the greater the likelihood that they will be miscible with each other. Therefore even though the primary references cited above do not describe selecting polymers based upon their solubility parameters the guidance to select polymers to be miscible based upon solubility parameters was well known at the time of applicants claimed invention. As described in the previous office action one of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Hossainey, Whitbourne, Sirhan or Atala in order to calculate which polymers are likely to form blends when mixed together.

It appears as though applicants are attempting to claim a well known and established scientific principle, the use of solubility parameters to predict solubility of polymers and active ingredients. Essentially applicants believe that the inventiveness of their claimed invention stems from the fact that like dissolves like, a well known and old scientific principle. As applicants are undoubtedly aware of by now, from the extended prosecution history of this case (four requests for continued examination), the examiner will not give patentable weight to claims directed to the well known scientific principle of mentally selecting ingredients that will be soluble with each other based on known solubility parameters. One of ordinary skill could simply find the solubility parameters of the claimed polymers and active agents in a book or software program. Therefore it is respectfully submitted that applicants, in order to save resources and time for themselves and the office to end the extremely long and

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lengthy prosecution of this case and appeal this application before the board of patent appeals and interference. Essentially there are no new arguments on either side of the prosecution (applicant's arguments and examiners response are now essentially cut and paste responses from previous actions), thus both sides are clearly at in impasse. In such cases such as the current application when there is a clear impasse it is recommended that applicants appeal before the board of patent appeals and interference.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618